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EXAMINER	
WIEKER, AMANDA FLYNN	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Amanda F. Wieker	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: #135. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore:

the shunt communicating with the left ventricle (at least claims 2, 25-26, 28 and 30);

the pump having an input connected to the first chamber, and an output connected to a volume of blood at lower pressure (claims 8 and 18);

the pump moving blood from a chamber to an aorta (claim 23); and

the pump moving blood from the left ventricle to the right atrium (claim 24) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: The amendments to the specification submitted on 28 September 2004 appear to be incorrectly labeled. For example, the amendment says to replace paragraph [24] with a new paragraph, however the new paragraph actually correlates to old paragraph [26]. Similarly, the amendment says to replace paragraph [26] with a new paragraph, however the new paragraph actually correlates to old paragraph [28]. An identical problem occurs with the amendments labeled for paragraphs [27] and [37], which correlate with paragraphs [29] and [39] instead.

Appropriate correction is required.

4. The amendment filed on 28 September 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

supported by the original disclosure is as follows: The subject matter of claims 24, 26, 28 and 30 constitute new matter.

The specification as originally filed did not disclose a pump that moves blood from the left ventricle to the right atrium during systole and diastole.

The specification as originally filed did not disclose the reduction of left ventricle pressure by 5 mmHg; or the reduction of left ventricular pressure by 5 mmHg, if the end diastolic pressure exceeds 25 mmHg and/or the mean left ventricle pressure exceeds 20 mmHg.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

5. Claims 26 and 27 are objected to because of the following informalities: There is insufficient antecedent basis for "the first portion". This structure is now referred to as a "first chamber".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 24, 26, 28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Claims 24, 26, 28 and 30 are rejected for containing new matter, as described above.

Claim 24, through its dependency on claim 8, recites a shunt comprising a pump, which outputs to a volume of lower pressure, and wherein said pump moves blood from the left ventricle to the right atrium during systole and diastole. This was not disclosed in the originally filed specification or drawings. The specification only discloses a "passive shunt" in relation to shunting between the left ventricle and right atrium (see [0038]). Clearly, a shunt including a pump is not a "passive shunt" and was not originally disclosed. As such, claim 24 incorporates new matter.

Claims 26, 28 and 30 recite the reduction of left ventricular pressure by exactly 5 mmHg, which was not disclosed in the originally filed specification. The specification or drawings as originally filed do not disclose this value. This material was disclosed in paragraphs [33-36] of the specification with relation to the left atrium, but not with respect to the left ventricle. The originally filed disclosure does not support this newly added material, and as such is considered new matter.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is rejected as being indefinite, because it is unclear what is included in the claim. The claimed subject matter is described in the specification at paragraph [37] in language

identical to that in claim 23. Despite a thorough reading of the specification, this limitation remains unclear.

The examiner is unsure what is meant by "moving blood from a chamber exhibiting at least 20 mmHg in diastole to at least 70 mmHg or more in the aorta". It is unclear if this claim is intended to mean that blood is moved from a chamber having 20 mmHg to an aorta having a pressure of 70mmHg. This is unclear, because claim 8 (from which claim 23 depends) requires that blood moves from a region of high pressure to one of low pressure. This is contrary to the limitation of claim 23, which requires moving blood from a chamber having 20 mmHg (low) to an aorta having a pressure of 70 mmHg (high). As such, it is unclear what is claimed by claim 23.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 4, 9-14, 19-22, 25, 27, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,458,153 to Bailey et al.

Bailey et al. disclose an apparatus (40) for decreasing pressure in a first chamber (LA) of the heart, the apparatus comprising a shunt including a fixation element (42, 44), a shunt tube element (11, 12) and a valve element (28), said valve element adapted to enable selectively

permitting blood flow between the first chamber and a second chamber (LV) at a selected pressure threshold (at a "positive pressure" that overcomes the bias exerted by the valve, to allow flow from LA toward LV; see column 8, lines 1-4 and column 11, lines 13-27).

The valve is a passive check-valve that is adapted to allow flow when a pressure differential between the chambers is between a lower threshold (zero; see column 8, lines 1-4) and a higher threshold ("positive pressure" that overcomes valve's bias), and whereby shunting is prevented during left ventricular systole (see Figure 12B and accompanying description).

The tubular element includes two ends and a tissue fixation element (42, 44) at each of the ends.

Bailey et al. specify that the tubular element may be comprised of a biologically inert non-metallic material (plastically deformable materials, super-elastic materials, graft; column 8, lines 4-8).

The claimed method of decreasing pressure in a first chamber (LA) of a vessel of a heart, comprising implanting a shunt (40) adapted to communicate with a second chamber (LV) outside the first chamber, whereby a volume of blood sufficient to reduce the pressure in the first chamber, when said pressure reaches a selected threshold ("positive pressure" to overcome valve's bias), is released from the first chamber to the second chamber, is anticipated by the normal use of the device disclosed by Bailey et al.

Flow is selectively permitted when a pressure differential exists between the first and second chambers, wherein the pressure differential is between a lower (zero) and higher ("positive pressure" enough to overcome valve's bias) threshold.

Bailey et al. further disclose the step of implanting of the shunt using a catheter (200, 501), such that the tissue fixation element is released. The tissue fixation elements of the stent body can be made of a shape memory metallic material.

The valve member of the shunt tube comprises more than one flat pivoting plate (leaflets 26).

Regarding claims 12, 27, 29 and 31, Bailey et al. disclose that the first chamber is the left atrium and the shunt communicates with the left atrium to reduce the left atrium pressure by a suitable amount, which is capable of being 5 mmHg, or any other desired amount depending on the application and the particular patient's needs. The biasing of the valve member is capable of being adjusted, such that the shunt releases blood from the first chamber to the second chamber to maintain the end diastolic pressure in the first chamber at 15 mmHg, or any other selected amount depending on the application and the particular patient's needs. Similarly, the device is capable of reducing left atrium pressure by 5 mmHg or any other amount, if the left atrium pressure exceeds 25 mmHg and/or the mean left atrium pressure exceeds 20 mmHg, or any other amount that overcomes the bias force of the valve depending on the application and the particular patient's needs. It is noted that Applicant does not disclose any criticality to reducing the pressure by only and exactly 5 mmHg, and as such, any reduction in pressure sufficient to meet the specific needs of the patient is anticipated by the Bailey et al. reference.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-2, 9-14, 19-22, 26, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,429,144 to Wilk.

Wilk discloses an apparatus for decreasing pressure in a first chamber (LV') of a heart comprising a shunt including a fixation element ("spring bias or memory"), a shunt tube element (66), and a valve element (68), said valve element adapted to enable selectively permitting blood flow between the first chamber (LV') and a second chamber (CA') of the heart at a selected pressure threshold, wherein the pressure threshold is that pressure which occurs at maximum systole, due to maximum contraction of the muscles of the left ventricle which overcomes the opposing pressure in the second chamber (CA'). Due to the increased pressure caused by the systolic contraction, the blood contained in the left ventricle is imparted with a higher pressure, which causes it to flow out the one-way valve, and into the second chamber (CA').

The shunt (66) communicates with the left ventricle (LV') to enable a volume of blood to be released from the left ventricle, and is capable of maintaining the end diastolic pressure in the left ventricle at 15 mmHg or less, or any other selected and desired end pressure as determined by the specific application and needs of the patient.

The tubular element includes two ends and a tissue fixation element disposed at each end.

The tubular element is comprised of a biologically inert non-metallic material (graft, for example).

The claimed method of decreasing pressure in a first chamber (LV') of a vessel of a heart, comprising implanting a shunt (66) adapted to communicate with a second chamber (CA') outside the first chamber, whereby a volume of blood sufficient to reduce the pressure in the

first chamber, when said pressure reaches a selected threshold (when said LV' pressure reaches maximum systolic pressure and overcomes the pressure in CA'), is released from the first chamber to the second chamber, is anticipated by the normal use of the device disclosed by Wilk.

The shunt (66) communicates with the first chamber (LV') to enable a volume of blood to be released from the first chamber, and is capable of maintaining the end diastolic pressure in the first chamber at 15 mmHg or less, or any other selected and desired end pressure as determined by the specific application and needs of the patient.

The method further comprises selectively permitting flow when a selected pressure differential exists between the first and second chambers, wherein that pressure differential is between a higher threshold (maximum systole) and a lower threshold (maximum diastole).

Wilk discloses implanting said shunt using a catheter such that the tissue fixation element is released. The tissue fixation elements of the stent body can be made of a shape memory metallic material.

Wilk discloses that the shunt tube further comprises at least two flat pivoting plates (68).

Regarding claims 12, 26, 28 and 30, Wilk discloses that the first chamber is the left ventricle and the shunt communicates with the left ventricle to reduce the left ventricle pressure by a suitable amount, which is capable of being 5 mmHg, or any other desired amount depending on the application and the particular patient's needs. The biasing of the valve member is capable of being adjusted, such that the shunt releases blood from the first chamber to the second chamber to maintain the end diastolic pressure in the first chamber at 15 mmHg, or any other selected amount depending on the application and the particular patient's needs. Similarly, the device is capable of reducing left ventricle pressure by 5 mmHg or any other

amount, if the left ventricle pressure exceeds 25 mmHg and/or the mean left ventricle pressure exceeds 20 mmHg, or any other selected amount depending on the application and the particular patient's needs. It is noted that Applicant does not disclose any criticality to reducing the pressure by exactly and only 5 mmHg, and as such, any reduction in pressure sufficient to meet the specific needs of the patient is anticipated by the Wilk reference.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 5, 7-8, 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of U.S. Patent Number 6,210,318 to Lederman.

Bailey et al. disclose the previously described shunt communicating from a first chamber (LA) to a second chamber (LV) outside the first chamber to reduce pressure in the first chamber as blood flows through the shunt. Bailey et al. specify that the shunt may have a one-way valve to permit flow from the first chamber. Bailey et al. do not specify that the valve be a semi-passive check valve. Bailey et al. also do not specify that the shunt include pumping means.

Lederman discloses a shunt and pumping balloon device that is placed in a first chamber of a patient's heart, to assist in the pumping of blood from the first chamber. The device comprises several valves, which may be semi-passive check valves operated by an extracorporeal controller and energy source to control the activation of the valves externally from the patient. The pumping balloon (102) is in fluid communication with the shunt (104) and

has an input connected to the first chamber, and an output connected to a volume of lower pressure.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Bailey et al., wherein the valve is a semi-passive check valve and the shunt includes a pump, as taught by Lederman, to control activation of the valves externally from the patient, and to assist the flow of blood from the first chamber. The claimed method of decreasing pressure is made obvious by the normal use of the device disclosed by Bailey et al. in view of Lederman.

16. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of U.S. Patent Number 6,632,169 to Korakianitis et al.

Bailey et al. disclose the previously described shunt communicating from a first chamber (LA) to a second chamber (LV) outside the first chamber to reduce pressure in the first chamber as blood flows through the shunt. Bailey et al. specify that the shunt may have a one-way valve to permit flow from the first chamber. Bailey et al. do not specify that the valve be a semi-passive check valve.

Korakianitis et al. disclose a left ventricular assist device that is placed in a first chamber of a patient's heart, to assist in the pumping of blood through the heart and body. The device comprises a semi-passive check valve operated by an intra-corporeal electrical battery such that the entire device can be contained within the body.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Bailey et al., wherein the valve is a semi-passive check valve, as taught by Korakianitis et al., such that the entire device can be contained within the

body. The claimed method of decreasing end diastolic pressure is made obvious by the normal use of the device disclosed by Bailey et al. in view of Korakianitis et al.

17. Claims 5, 7-8, 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of U.S. Patent Number 6,210,318 to Lederman.

Wilk discloses the previously described shunt communicating from a first chamber (LV') to a second chamber (CA') outside the first chamber to reduce pressure in the first chamber as blood flows through the shunt. Wilk specifies that the shunt may have a one-way valve to permit flow only from (not into) the left ventricle. Wilk does not specify that the valve be a semi-passive check valve. Wilk also does not specify that the shunt include pumping means.

Lederman discloses a shunt and pumping balloon device that is placed in a patient's left ventricle, to assist in the pumping of blood from the ventricle. The device comprises several valves, which may be semi-passive check valves operated by an extracorporeal controller and energy source to control the activation of the valves externally from the patient. The pumping balloon (102) is in fluid communication with the shunt (104) and has an input connected to the left ventricle, and an output connected to a volume of lower pressure.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Wilk wherein the valve is a semi-passive check valve and the shunt includes a pump, as taught by Lederman, to control activation of the valves externally from the patient, and to assist the flow of blood from the first chamber. The claimed method of decreasing pressure is made obvious by the normal use of the device disclosed by Wilk in view of Lederman.

18. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of U.S. Patent Number 6,632,169 to Korakianitis et al.

Wilk discloses the previously described shunt communicating from a first chamber (LV') to a second chamber (CA') outside the first chamber to reduce pressure in the first chamber as blood flows through the shunt. Wilk specifies that the shunt may have a one-way valve to permit flow only from (not into) the left ventricle. Wilk does not specify that the check valve be a semi-passive check valve.

Korakianitis et al. disclose a left ventricular assist device that is placed in a patient's left ventricle, to assist in the pumping of blood through the heart and body. The device comprises a semi-passive check valve operated by an intra-corporeal electrical battery such that the entire device can be contained within the body.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Wilk wherein the check valve is a semi-passive check valve, as taught by Korakianitis et al., such that the entire device can be contained within the body. The claimed method of decreasing end diastolic pressure is made obvious by the normal use of the device disclosed by Wilk in view of Korakianitis et al.

Response to Arguments

19. Applicant's arguments filed on 28 September 2004 have been fully considered but they are not persuasive.

20. On page 13 of the Remarks, Applicant argues that the Wilk patent does not disclose extending a stent between "chambers" of the heart. The examiner disagrees. As noted in Applicant's specification, for example at page 11, Applicant recites that the "pump continuously moves a small amount of blood from one chamber or area to another, for example from the left ventricle chamber to the aorta". Based on this description, it appears that Applicant considers a vessel such as the aorta to be a "chamber" and as such, the coronary artery also constitutes a

"chamber". Therefore, the Wilk patent clearly discloses a stent that extends from one chamber to another, specifically, from the left ventricle to the coronary artery.

Further, upon examining a dictionary definition of the word "chamber", the examiner finds additional support for the belief that the coronary artery is in fact a "chamber" (see included definition of "chamber", from Merriam-Webster OnLine Dictionary). The cited dictionary definition defines chamber as "a natural or artificial enclosed space or cavity". The coronary artery meets this definition, as it is a "natural enclosed space", and as such is considered to be a "chamber".

21. On pages 13-14 of the Remarks, Applicant argues that the Wilk patent does not disclose using pressure thresholds for selectively controlling blood flow through a valve from a first to a second chamber of the heart.

Initially, the examiner notes that the instant rejections to Wilk are formulated differently from those of the previous office action, as necessitated by Applicant's amendment. Nonetheless, as far as Applicant's arguments are still relevant to the outstanding rejections, the examiner will discuss them here.

The examiner disagrees with Applicant's contention that the Wilk patent does not disclose using pressure thresholds for selectively controlling blood flow through a valve from a first to a second chamber of the heart. As discussed above, Wilk discloses a shunt (66) having a valve (68) that is adapted to enable selectively permitting blood flow from a first chamber (LV') to a second chamber (CA') at a preselected pressure threshold, wherein that pressure threshold is that pressure which occurs at maximum systole, due to maximum contraction of the muscles of the left ventricle. Due to the increased pressure caused by the systolic contraction, the blood contained in the left ventricle is imparted with a higher pressure, which causes it to flow out the

one-way valve, and into the second chamber. The blood has been imparted with high enough pressure to overcome the opposing pressure in the second chamber, which had been acting on the valve. As noted, immediately after the systolic ejection of high-pressure blood from the left ventricle, the valve (68) closes in response to the now low pressure remaining in the left ventricle, to prevent blood from flowing backward from the second chamber (CA') to the first (LV'). Despite Applicant's assertions, a pressure differential necessarily exists to affect the disclosed function of the one-way valve.

As currently drafted, the Wilk reference is believed to meet the claim limitations requiring using pressure thresholds (high ventricular systolic pressure versus low ventricular diastolic pressure) for selectively controlling blood flow through a valve from a first to a second chamber of the heart.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda Wieker

Amanda F. Wieker
Examiner
Art Unit 3743

afw

Henry Bennett
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